DETAILED ACTION

Applicants' response filed 7/25/2008 has been received. Claims 38, 39, 41-48, 53, 54, 65, 68-79 and 81-87 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 68 and 82-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims now specify the "weight average molecular weight" of polyvinylpyrrolidone. The original disclosure does not mention the "weight average molecular weight" of the polyvinylpyrrolidone, nor is there any discussion of what type of molecular weight is referred to in the original disclosure. The introduction of this limitation therefore constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38, 39, 41, 45-48, 65, 69, 71-79, 81 and 87 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0018071 to Rennard in view of US 6,667,362 to Ghebre-Sellassie and Remmington for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive.

Applicants' first attack the teachings of the three references individually, and then conclude that the invention is not obvious. This is not persuasive because a holding of obviousness based on combination of references cannot be overcome by looking at the references individually; the proper test is what the references in combination teach the artisan. Applicants' then allege that Ghebre-Sellassie teaches only solvent-free methods, and that this teaches away from the requirement of using aqueous PVP in instant claims. In response, the teaching of a preferred or favored embodiment is not a teaching away from alternative embodiments, nor does a reference that omits one element of a combination (or method), without more, teach away. *See Syntex (U.S.A) LLC v. Apotex, Inc.*, 74 USPQ2d 1823, 1830 (Fed. Cir. 2005) (specifically enumerating useful surfactants is not a teaching away from the use of other surfactants). In this case, the reference teaches only solvent free formulation, and is silent on aqueous formulation. It is an error to construe the reference's silence on these alternatives as teaching away from the alternatives (*See id.*) This is especially true in view of Remmington's teachings that aqueous polymers can be granulated effectively.

Applicants then look again at the Ghebre-Sellassie reference alone and find it lacking, but this is unpersuasive because it does not take into account the other references. The statement that "[n]either does the combination of references correct these deficiencies…" is merely conclusory.

Applicants continue by pointing to the Chiou teaching and allege that it teaches away from the instant claims because it teaches that PVP dispersions should be prepared by a solvent method, and that PVP is soluble in a variety of organic solvents. In this line of reasoning, Applicants have failed to recognise that PVP is also well known to be water soluble (for example, the PVP technical listed on the 2/27/2008 PTO 892 notes that PVP is soluble in water). As such, contrary to Applicants' comments, the artisan looking at Chiou's suggestion of using a solvent in which PVP is soluble, and knowing that PVP is soluble in water, would clearly find it obvious to use water as the granulating liquid. Applicants' conclusion that Chiou somehow teaches away from the claims is not well founded. Indeed, contrary to Applicants' comments, the artisan following Chiou would expect such a method to be successful.

Applicants' final argument relates to unexpected results alleged on page 11 of the specification. These results relate to the bioavailability of the drug in the product produced by the instant process. The Office is unable to evaluate these alleged unexpected results, because there is no data of record comparing the dosages made by methods of the instant claims to those of the closest prior art. Applicants' appear to allege here that unobviousness is based on some unexpected result stemming from the

use of aqueous granulation over solvent free granulation. However, there is no evidence of record to support this allegation and it therefore cannot be persuasive.

Claims 68 and 82-84 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard in view of Ghebre-Sellassie, Remington, and US 5,262,711 to Login.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants' first argue that "[t[here is no indication [in Login] if the tablets are 89-99% acetaminophen, or if other fillers or bonders [sic: binders] are also employed." This argument is not well understood, as it is not clear how it relates to Login's teaching of the appropriate molecular weight of PVP for use in tablets. Nor are applicants' next arguments, that Login is not clear about how the tablets were made and is not clear about whether aqueous PVP is used, relevant to Login's teachings of the appropriate molecular weight of PVP. Furthermore, it is not clear why Applicant does not believe that Login is combinable with the other references; other references teach the use of PVP in tablets but are silent on the molecular weight, Login provides an appropriate molecular weight and thus is properly combinable.

Claims 42-44, 53, 54, 85, and 86 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard in view of Ghebre-Sellassie, Remington and Chiou et al, 1971.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants repeat the arguments from the earlier rejection of claims over Rennard, Ghebre-Sellassie and Remington, including the arguments against Chiou. These arguments were all addressed above.

Claims 68, 70 and 82-84 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rennard in view of Ghebre-Sellassie, Remington, and Hatzelmann, 2001.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Hatzelmann does not overcome the alleged deficiencies in Rennard, Ghebre-Sellassie and Remington. Those supposed deficiencies were addressed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman
Art Unit 1618